

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew C. Karaplis et al.  
 Serial No.: 09/806,110  
 I.A. Filing Date: 27 September 1999  
 For: USE OF PEX IN THE TREATMENT OF METABOLIC  
 BONE DISEASES  
 Attorney Docket No.: 109.647.121

Box PCT  
 Assistant Commissioner for Patents  
 Washington, D.C. 20231

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN  
 THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Sir:

In response to the Notice to Notification of Missing Requirements Under 35 U.S.C. 371 mailed 1 May 2001 in connection with the above-identified application, Applicants enclose herewith an executed Declaration and Power of Attorney.

In addition, the Commissioner is authorized to charge the surcharge of \$65.00 (small entity fee) for the late filing of the Declaration to Deposit Account No. 08-0219. A Fee Transmittal is annexed herewith.

Finally, as required, a copy of Form PCT/DO/EO/905 is also enclosed.

In the event of a fee deficiency or an overpayment, the Commissioner is authorized to make the necessary adjustment(s) to Deposit Account No. 08-0219.

09/05/2001 LLANDGRA 00000071 080219 09806110  
 01 FC:254 65.00 CH

Dated: 31 August 2001

Respectfully submitted,

*Hollie L. Baker*

Hollie L. Baker  
 Registration No. 31,321  
 Attorney for Applicants

Hale and Dorr LLP  
 60 State Street  
 Boston, Massachusetts 02109  
 (617) 526-6000 (Telephone)  
 (617) 526-5000 (Facsimile)

Express Mail mailing label number EL641283855US  
 Date of Deposit 31 August 2001

I hereby certify that this correspondence and the enclosures referenced herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above, in an envelope addressed to Box PCT, Commissioner for Patents, Washington, D.C. 20231.


*Tina M. Dougal*  
 Tina M. Dougal

Please type a plus sign (+) inside this box → ☐Approved for use through 09/30/2000. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	<b>Application Number</b>	09/806,110
	<b>Filing Date (I.A.)</b>	27 September 1999
	<b>First Named Inventor</b>	Karaplis et al.
	<b>Group Art Unit</b>	
	<b>Examiner Name</b>	
<b>Total Number of Pages in This Submission</b>		<b>Attorney Docket Number</b> 109.647.121

ENCLOSURES (check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> Request for Refund	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below) <input checked="" type="checkbox"/> Postcard
<b>Remarks</b> 1. Response to Notification of Missing Requirements Under 35 USC 371 2. Executed Declaration 3. Return Copy of Form PCT/DO/EO/905 4. Petition for Extension of Time (Three Months)		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
<b>Firm or Individual name</b>	Hollie L. Baker, Registration No. 31,321 Hale and Dorr LLP, 60 State Street, Boston, MA 02109
<b>Signature</b>	<i>Hollie L. Baker</i> 
<b>Date</b>	August 31, 2001 <b>23483</b>

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: 8-31-01			
<b>Typed or printed name</b>	Tina M. Dougal		
<b>Signature</b>	<i>Tina M. Dougal</i>	<b>Date</b>	8-31-01

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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**FEE TRANSMITTAL  
for FY 2001**

Patent fees are subject to annual revision.

**Complete if Known**

Application Number	09/806,110
Filing Date (I. A.)	27 September 1999
First Named Inventor	Andrew C. Karaplis et al.
Examiner Name	
Group Art Unit	
Attorney Docket No.	109.647.121

TOTAL AMOUNT OF PAYMENT (\$ 510.00)

**METHOD OF PAYMENT**

- 1.
- ☒
- The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit  
Account  
Number

08-0219

Deposit  
Account  
Name

Hale and Dorr LLP

- ☒
- Charge Any Additional Fee Required
- 
- Under 37 CFR 1.16 and 1.17

- ☒
- Applicant claims small entity status.
- 
- See 37 CFR 1.27

- 2.
- ☐
- Payment Enclosed:

☐ Check ☐ Credit card ☐ Money  
Order ☐ Other**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
101	710	201	355	Utility filing fee	
106	320	206	160	Design filing fee	
107	490	207	245	Plant filing fee	
108	710	208	355	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) (\$ 0)

**2. EXTRA CLAIM FEES**

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	- 3** =	X	

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description
103	18	203	9	Claims in excess of 20
102	80	202	40	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim, if not paid
109	80	209	40	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)

(\$ 0)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	65.00
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for <i>ex parte</i> reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	445.00
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,240	241	620	Petition to revive - unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1.17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 510.00)

**SUBMITTED BY**

Name (Print/Type)

Hollie L. Baker

Registration No.  
(Attorney/Agent)

31,321

**Complete (if applicable)**

Telephone

617-526-6110

Signature

*Hollie L. Baker*

Date

Aug. 31, 2001

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/806110

KARAPLIS  
HALE AND DORR LLC

A

SWA-XXX

INTERNATIONAL APPLICATION NO.

PCT/CA99/00895

I.A. FILING DATE

PRIORITY DATE

27 SEP 99

28 SEP 98

DATE MAILED: 01 MAY 2001

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> U.S. Basic National Fee.   | <input type="checkbox"/> Indication of Small Entity Status.                         |
| <input checked="" type="checkbox"/> Copy of the international application.   | <input type="checkbox"/> Translation of the international application into English. |
| <input type="checkbox"/> Oath or Declaration of inventors(s).  | <input type="checkbox"/> Translation of Article 19 amendments into English.         |
| <input type="checkbox"/> Copy of Article 19 amendments.  | <input type="checkbox"/> Other:   |
| <input checked="" type="checkbox"/> Priority Document.   |   |
| <input checked="" type="checkbox"/> The International Preliminary Examination Report in English and its Annexes, if any. |   |
| <input type="checkbox"/> Translation of Annexes to the International Preliminary Examination Report into English.        |   |

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee. ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
- ☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$ \_\_\_\_\_ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

***A copy of this notice MUST be returned with this response.***